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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,969	09/11/2003	Wael R. Joseph	KCC 4979.1 (K-C 5031 19,378B)	
321 7590 07/31/2007 SENNIGER POWERS ONE METROPOLITAN SQUARE 16TH FLOOR ST LOUIS, MO 63102		•	EXAMINER	
			AHMED, HASAN SYED	
			ART UNIT	PAPER NUMBER
	,		1615	
			r	
•			NOTIFICATION DATE	DELIVERY MODE
			07/31/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@senniger.com

		•			
	Application No.	Applicant(s)			
	10/659,969	JOSEPH ET AL.			
Office Action Summary	Examiner	Art Unit			
	Hasan S. Ahmed	1615			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be tin rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status					
1) Responsive to communication(s) filed on 09 M	ay 2007.				
,					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims		•			
4) Claim(s) 1-8,10,12-33,35-40,42 and 44-61 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed. 6) Claim(s) <u>1-8,10,12-33,35-40,42 and 44-61</u> is/a	re rejected	•			
7) Claim(s) is/are objected to.	re rejected.	·			
8) Claim(s) are subject to restriction and/or	r election requirement.				
Application Papers					
9) The specification is objected to by the Examiner.					
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).					
a) All b) Some * c) None of:					
 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 					
 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage 					
application from the International Bureau (PCT Rule 17.2(a)).					
* See the attached detailed Office action for a list of the certified copies not received.					
Attachment(s)					
1) Notice of References Cited (PTO-892)	4) Interview Summary	/ (PTO-413)			
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail D				
3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 3/20/07. 5) Notice of Informal Patent Application 6) Other:					

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DETAILED ACTION

 Receipt is acknowledged of applicants': (1) supplemental IDS (filed on 20 March 2007); (2) amendment (filed on 9 May 2007); and (3) request for continued examination (filed on 9 May 2007).

 The 35 USC 112 rejection of the previous Office action is withdrawn in view of the remarks.

Applicants correctly point out that the citation of U.S. Patent No. 4,556,660 in the
 "Response to Arguments" section of the previous Office action was a typographical
 error. Applicants correctly assume that the citation being referred to was U.S.
 Patent No. 4,556,560.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9 May 2007 has been entered.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 1. Claims 1-8, 10, 12-23, 25-33, 35-40, 42, 44-56, and 58-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vega, *et. al.* (U.S. Patent No. 6,153,209).

Vega, et. al. teach an absorbent product (see col. 1, line 7). The absorbent product disclosed is comprised of:

- the moisturizing and lubricating compositions of instant claims 1 and 32 (see col. 25, line 65 col. 26, line 14);
- the emollient of instant claim 1 (see col. 15, line 26);
- the humectant of instant claims 1 and 32 (see col. 25, line 65 col. 26, line 14);
- the immobilizing agent of instant claims 1 and 32 (see col. 26, line 6);
- the compatibilizing agent of instant claims 1 and 32 (see col. 26, line 5);
- the vegetable oil of instant claim 2 (see col. 15, lines 53-54]);
- the dimethicone of instant claims 3 and 35 (see col. 26, line 38);
- the glycerin of instant claims 5-7 and 37-39 (see col. 26, line 4);
- the polyethylene glycol of instant claims 1,10, 32, and 42 (see col. 26, lines 6-7);
- the butylene glycol of instant claims 12 and 44 (see col. 26, line 5);
- the dispersing agent of instant claim 13 (see col. 20, line 27);

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- the polydimethylsiloxane of instant claim 14 (see col. 20, line 27);
- the skin barrier enhancing agent of instant claims 16 and 46 (see col. 17, line 66 col. 18, line 10);
- the coconut oil of instant claims 17 and 47 (see col. 18, line 5);
- the tocopherol of instant claims 19, 20, 49, and 50 (see col. 19, lines 25-26);
- the cholesterol of instant claims 21, 22, 51, and 52 (see col. 18, line 13);
- the ceramide of instant claims 23 and 56 (see col. 17, lines 29);
- the surfactant of instant claims 25 and 53 (see col. 25, line 56); and
- the diapers of instant claims 31 and 61 (see col. 1, line 7).

Vega, et. al. explain that combining the disclosed ingredients into one absorbent product is beneficial because it provides, "...a breathable, protective barrier that keeps body exudates and other irritants from direct contact with the skin yet allows water vapor to pass through." See col. 1, lines 22-27.

Vega, et. al. do not explicitly teach use of the dispersing agent of instant claim 34 (Dow Corning® 5329). Rather, they teach use of the dispersing agent Dow Corning® 2503 (see col. 20, line 50). Because both Dow Corning® 5329 and Dow Corning® 2503 are functionalized dimethicones (see Dow Corning® product literature), one of ordinary skill in the art would have been motivated to add either Dow Corning® 5329 or Dow Corning® 2503 to the instant absorbent product. There is a reasonable expectation that the addition of either Dow Corning® 5329 or Dow Corning® 2503 to the instant absorbent product would provide an effective dispersing agent. As such, it would have

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been obvious to one of ordinary skill in the art at the time the invention was made to add either Dow Corning[®] 5329 or Dow Corning[®] 2503 to the instant absorbent product.

Vega, et. al. do not explicitly teach all the percentages recited in instant claims 1, 4, 8, 15, 18, 21, 32, 36, 40, 45, 48, and 51 (or the ratio recited in instant claim 33), however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage ranges.

The Vega, et. al. reference is silent with respect to the (1) phase temperatures of instant claims 1, 28-30, 32 and 58-60; (2) melting point of instant claims 26 and 54; (3) and penetration hardness of instant claims 27 and 55. Applicant's article is the same as the prior art. It contains the same components in the same configuration. Properties are the same when the structure and composition are the same. Thus, burden shifts to applicant to show unexpected results, by declaration or otherwise. *In re Fitzgerald*, 205

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USPQ 594. In the alternative, the claimed properties would have been present once the composition was employed in its intended use. *In re Best*, 195 USPQ 433.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine an emollient, a humectant, an immobilizing agent, and a compatibilizing agent into an absorbent product, as taught by Vega, *et. al.* One of ordinary skill in the art at the time the invention was made would have been motivated to combine these ingredients into an absorbent product because they allow for the formation of a breathable, protective barrier that keeps body exudates and other irritants from direct contact with the skin, while allowing water vapor to pass through, as explained by Vega, *et. al.*

2. Claims 1, 24, 32, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vega, et. al. (U.S. Patent No. 6,153,209) in view of Bowser, et. al. (U.S. Patent No. 5,342,976).

Vega, et. al. teach an absorbent product (see above).

The Vega, et. al. reference differs from the instant application in that it does not teach the glucosylceramide of instant claims 24 and 57.

Bowser, et. al. teach a skin composition that may be used in an absorbent product, such as a tissue wipe (see col. 16, line 44).

The disclosed composition contains the glucosylceramide of instant claims 24 and 57 (see col. 1, line 67).

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Bowser, et. al. explain that a ceramide, such as glucosylceramide, is beneficial in a skin composition because, "...when applied topically to the skin, bring(s) about a marked improvement in skin condition, by enhancing skin barrier function." See col. 2, lines 7-9.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to add glucosylceramide to an absorbent product, as taught by Vega, et. al. in view of Bowser, et. al. One of ordinary skill in the art at the time the invention was made would have been motivated to this ingredient into a tissue product for the beneficial effect of enhancing skin barrier function, as explained by Bowser, et. al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8, 10, 12-33, 35-40, 42, and 44-61 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-59 of copending Application No. 10/659,862 ('862). Although the conflicting claims are not identical, they are not patentably distinct from each other because '862 claims a tissue product comprising a moisturizing and lubricating composition comprising an emollient, a humectant, an immobilizing agent, and a compatibilizing agent. See claim 1.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments regarding the 35 USC 103 rejection, filed on 9 May 2007, have been fully considered but they are not persuasive.

1. Applicants argue, "...Vega, et al., however, fail to teach or suggest compositions comprising from about 1% (by weight) to about 40% (by weight) of these compounds or of compatibilizing agents generally." See remarks, page 24.

Examiner respectfully submits that applicants are claiming a very broad range, i.e. 1% - 40% by weight. Applicants show no criticality of the claimed range.

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Applicants direct the record to paragraph 66 of the instant application to show, "...the compatibility of the moisturizing and lubricating compositions of the present invention is important for the processability and stability of the compositions." See remarks, page 25. However, the cited language is directed to the compatibility of compositions in the mixing process, not a particular concentration range of compatibilizing agent; it does not specifically address why the broad range of 1%-40% of compatibilizing agent is critical.

2. Applicants argue that the benefits of compatibilizing agents are not disclosed or recognized by the Vega reference. See remarks, page 25, last paragraph.

Vega teaches compatibilizing agents (see col. 26, line 5). The description of "compatibilizing agent" at paragraph 65 of the instant specification recites propylene glycol and low molecular weight polyethylene glycols as appropriate compatibilizing agents, both of which are disclosed in the Vega, et al. reference (see col. 26, lines 5-7). Examiner respectfully submits that any benefits of compatibilizing agents are an inherent feature of said agents.

Applicants argue that, "... the '560 patent is cited by Vega, et al. as describing a non-limiting example of skin care agents that may be used in the compositions of Vega, et al." Emphasis omitted. See remarks, page 28.

MPEP 2163.07(b) states:

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Instead of repeating some information contained in another document, an application may attempt to incorporate the content of another document or part thereof by reference to the document in the text of the specification. The information incorporated is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed. Replacing the identified material incorporated by reference with the actual text is not new matter (emphasis supplied).

Examiner respectfully submits that Vega incorporates the whole '560 reference by reference. As such the '560 teaching of using high molecular weight polyethylene glycols in an absorbent product should be treated as part of the Vega reference.

Furthermore, the '560 teaching of using high molecular weight polyethylene glycols in an absorbent product shows that use of high molecular weight polyethylene glycols in absorbent products was well known in the art before the filing of the instant application.

4. Applicants argue that, "...it appears that the Office has used impermissible hindsight analysis and reconstruction when modifying the cited reference." See remarks, page 30.

Examiner respectfully submits that it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning.

But so long as it takes into account only knowledge which was within the level of

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ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Examiner respectfully submits that the prior art teaches an absorbent product containing the claimed ingredients.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HUMERA N SHEIKH PRIMARY EXAMINER